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November 6, 2008

Water Docket
Environmental Protection Agency
Mailcode: 4023M
1200 Pennsylvania Ave., NW
Washington, DC 40460

Attention: **Docket ID No. EPA-HQ-QW-2008-0517**

The American Health Care Association and the National Center for Assisted Living (AHCA/NCAL) would like to work with the Environmental Protection Agency (EPA) on finding solutions for the disposal of unused pharmaceuticals, since we agree this issue should be addressed from a federal perspective. However, AHCA/NCAL is concerned about this particular initiative singling out the health care industry, for we strongly believe the contamination of ground water by pharmaceutical compounds is a national, multi-faceted problem with numerous other originating sources, such as agriculture. Thus, this problem must be addressed comprehensively and cooperatively at the national, state and local levels, rather than focusing just on health care providers. Furthermore, this issue also needs to be understood within the context of our nation's overall health care system and long term care (LTC) is just one small part – especially since the majority of pharmaceuticals are taken by people in their own homes or workplaces within local communities, and not institutional settings.

EPA needs to recommend a common disposal system. Americans need a solution, not a government survey. As such, AHCA/NCAL recommends EPA consider the following before implementing the proposed survey:

- Work with environmental scientists to help determine the most environmentally sound method for the disposal of unused pharmaceuticals. Currently methods to be evaluated include incineration, discharge into sewer, disposal via ground waste, and recycling.
- Once the scientists have evaluated methods and determined the best method of disposal, develop a common direction for a national standardized drug disposal practice that includes controlled substances.
- Work with other government agencies and state pharmacy boards to evaluate current state level restrictions and to prevent duplicity and conflict with EPA's recommended direction, disposal practices and redistribution processes.
- Eliminate the proposed questionnaire since the requested data will not offer information that brings us closer to a solution.
- If the EPA must employ a questionnaire, substantially simplify the survey to improve information accuracy and to decrease the burden experienced by health care facilities during completion.

To frame this issue, in terms of prescription medications in our nation, utilization jumped over the last decade, from an average of 8.9 per person, per year in 1997 to 12.6 in 2007 according to the Kaiser Family Foundation (http://www.kff.org/rxdrugs/upload/3057_07.pdf). We are cognizant of the positive correlation between increases in age and drug utilization (<http://www.statehealthfacts.org/comparemaptable.jsp?ind=265&cat=5>). It is important to put the demographics in perspective, given that only 0.47 % of all Americans across the lifespan are nursing home patients. With regard to those 65 and older, the percentage is higher – 3.6 %, with the significant majority still in the community. Therefore, it is imperative that other stakeholders, including Medicare Part D plans and pharmaceutical manufacturers, need to be involved in the solution.

Within the specific context of the LTC profession, AHCA/NCAL's overreaching goal is to help identify, evaluate, and disseminate ways to dispose of unused medications in order to protect the environment and human health, while being cost effective and appropriate to the way LTC facilities operate within the confines of both state and federal regulations and statutes. Providers are looking for more guidance on best practices for the disposal and/or reuse of unused medications.

We are concerned about the proposed survey, both in terms of specific questions and its purpose. The stated purpose of the survey is to identify how LTC providers dispose of medications, but it will neither determine the best disposal methods for medications nor disseminate any existing promising practices to providers. Providers believe that guidance is needed on how best to dispose of controlled substances, out-of-date drugs, ointments, partially used IV fluids, etc and believe guidance can be provided without the need for a costly survey. If a survey must be used for the long term care setting, it needs to be less complex and more geared to how facilities operate and staff. For example, LTC facilities administer both prescription drugs prescribed for a specific patient as well as other pharmaceuticals purchased as stock, which are not patient-specific, like acetaminophen (Tylenol), ibuprofen (Motrin), vaccines for Influenza and Pneumococcal, skin protection ointments (A&D), and sometimes controlled substances that are given without an individualized stock. Thus, not all medication orders result in disposal of unused medications.

AHCA/NCAL offer EPA information from our own June 2008 survey that was completed by our state affiliates. It queried for the methods members use to dispose of unused medication, the method members use to dispose of controlled substances, and the presence of state laws or efforts regarding medication destruction. We believe this survey information will augment an abbreviated EPA survey (if the survey must be done) for LTC.

The EPA's proposed survey is too long and will be burdensome for LTC facilities to complete. LTC facilities are small businesses. Nationwide, there are approximately 15,762 skilled nursing facilities, with a median occupancy of 89% or averaging 90 patients per facility. The clinical staff in nursing homes consists of registered nurses (RNs), licensed practical nurses (LPNs), and certified nursing assistants (CNAs). When looking at the LTC clinical workforce, the average number of full-time equivalents is RNs – 5.8, LPNs – 14.3, and CNAs – 42.5. The professional nursing workforce not only provides care to patients, but manages the other caregiving staff as well. In nursing homes, for example, most of the burden to collect the proposed information will fall on the Director of Nursing (DoN) since most Medical Directors are not at the facility on a daily basis and many Administrators are not in the building on an everyday basis. The DoN is responsible for the day-to-day care provided to patients, clinical operations, and adherence to regulatory requirements. The role and accountabilities of the DoN (particularly when there is no formal back-up for this position) do not leave the DoN with the needed time to complete a lengthy survey.

Moreover, the cost associated with the preparation of the response to the draft survey by a DoN, using 41 hours as a response time as experienced by hospitals, is approximately \$1,450 for each nursing facility. We believe the response time is underestimated for nursing facilities.

Nurse staffing in assisted living facilities is generally less intensive than nursing homes; while larger facilities may have a nurse on staff, nursing services are often contracted on a part-time basis and typically involve supervising and reviewing operation issues rather than providing direct care services. In assisted living facilities, the task of managing medications and helping residents administer medications is typically performed by front line personal care aids, often with special training. Staff in assisted living facilities often have busy schedules and report having difficulty being able to reserve time to complete lengthy surveys. Even more than frontline staff in nursing homes, assisted living staff may lack the expertise to answer many questions about medications.

Why are national recommendations, encompassing institutional and community-dwelling elders, needed for the disposal of unused pharmaceuticals? While we acknowledge the elderly (whether the small minority who are institutionalized or the vast majority living at home) account for 1/3 of prescription drug use in the U.S. According to the UCSF Division of Geriatric Primary Care Lecture Series called *Drugs and the Elderly: Practical Considerations*, conducted by C. Bree Johnson, MD, MPH in May 2001 and found at http://74.125.45.104/search?q=cache:jwmHywIO4CoJ:www.ucop.edu/agrp/docs/sf_drugs.ppt+medications+and+the+elderly&hl=en&ct=clnk&cd=3&gl=us, ambulatory elderly fill between 9 – 13 prescriptions a year (new and refills) and average about 6 prescription medications per year. Nursing home patients average 7 prescription medications. In a survey, it was found that ambulatory elderly take 2 to 4 non-prescription drugs daily. In addition, the use of complementary therapies such as herbals is common in the ambulatory elderly. For example, growth hormone for anti-aging, ginkgo biloba for dementia, saw palmetto for benign prostatic hypertrophy, chondroitin sulfate and glucosamine for osteoarthritis, and St. John's wort for depression. While the herbal remedies offer a more natural intervention for common elderly conditions, the California Department of Health Services, Food and Drug Branch found differently. The branch screened 250 Asian herbal products collected from stores in the State and found 32% contained unlabeled medications, 14% mercury, 14% arsenic and 10% lead. Considering the amount of drug use in the elderly, it is apparent that potential water contamination from excreted and unused drugs is likely greater in community-dwelling elders as among those who are institutionalized, in the aggregate.

Moreover, in looking at the amount of drugs in ground water and waste water systems, it is necessary to consider the drugs that are taken but excreted from the body unchanged. While most drugs are metabolized first prior to being excreted, some drugs, such as aminoglycoside antibiotics are polar compounds and are excreted by the kidneys without being metabolized first. According to *Drug Therapy in the Elderly*, Table 1: *Effects of Aging on Drug Metabolism and Elimination*, published by Merck and found at <http://www.merck.com/mmpe/sec20/ch306/ch306a.html>, “polar compounds, which include most drug metabolites, cannot diffuse back into the circulation and are excreted unless a specific transport mechanism exists for their reabsorption (e.g., as for glucose, ascorbic acid, and B vitamins). With aging, renal drug excretion decreases at age 80, clearance is typically reduced to ½ of what it was at age 30.” It is clear that water contamination from excreted drugs is not primarily associated with the elderly. In nursing homes and assisted living facilities, the average resident is about 85 years of age.

Today, national long term care policy efforts are focused on care delivery in home and community-based settings. In fact, the average length of stay for patient receiving rehabilitation and skilled services in nursing homes is approximately 25 - 29 days. Currently, the short-stay nursing home population accounts for 13% of total patients. Keep in mind that Dr. Bree Johnson

reported that the amount of drugs used by the elderly ambulatory population is about 10 prescriptions and non-prescription drugs daily compared to 7 prescription drugs daily for individuals in nursing homes. Considering the amount of drugs used by ambulatory elders and nursing home patients and the reduced capacity of elderly to excrete drugs via the renal system, it is not logical for EPA to focus on pharmaceutical disposal in waste water emanating solely from long term care settings. A more global approach that includes all industries and households needs to be the focus of efforts to eliminate or reduce medication contamination in waste water systems.

For example, a recent article in Environmental Health Perspectives entitled “Impacts of Waste from Concentrated Animal Feeding Operations on Water Quality” (Volume 115, Number 2, February 2007, 308-312) reports that animals in agricultural livestock operations generate roughly 133 million tons of biological excrement, each year-- thirteen times more than that produced by all human residents of the United States. It is important to note that the authors cite EPA as the source for that incredible statistic. Indeed, the article also notes that of all the antibiotics consumed in our nation, one-third is ingested by livestock. The authors conclude that current industry practices “do not adequately or effectively protect water resources from contamination with excessive nutrients, microbial pathogens, and pharmaceuticals present in the waste.” Thus, while AHCA/NCAL strongly believe that long term care providers must play their role in the good stewardship of our environment, we also hold that solutions should be created and implemented in context so that the most emphasis is placed the greatest contributors to the problem at hand—which is not long term care facilities.

In closing, the EPA reports that the goal for unused pharmaceutical disposal analysis is to determine the current disposal methods for unused pharmaceuticals at medical facilities, to identify and evaluate potential alternative disposal methods and compare disposal practices across the nation. AHCA/NCAL believes that EPA can achieve these goals simply by surveying states for mandated disposal methods and for state-wide program implementation, as well as interviewing experts in the field. A much simpler, shorter and less invasive survey could be used to identify the type of drugs disposed of on a regular basis. For example, facility ownership and revenues can be obtained from other records such as Medicare Cost Reports rather than asking for the information to be repeated on a survey.

The purposes of the proposed survey are not consistent with all the information requested. It is unclear why EPA wants to know about specific facility policies for drug disposal, the number of employees, and where medications are obtained and where stored, when the survey is trying to assess the type and number of drugs disposed of via waste water systems. The proposed survey questions are not all clearly related to the reported goal for data collection and our members have expressed concern that data collection may be used for other purposes not yet made known. To offset concern and not just those concerns related to facility finances, will the EPA allow the entire survey response to be classified as Confidential Business Information?

We have included specific comments and recommendations on the following pages.

AHCA/NCAL greatly appreciates the opportunity to meet with EPA and discuss the need to determine a best method for the disposal of unused pharmaceuticals and a national direction. If EPA must use a survey, we welcome the opportunity to help redesign a survey more appropriate for LTC. LTC providers are looking for guidance and a cost-effective direction that is environmentally sound and nationally accepted by all states and governing entities.

Sincerely,



Sandra Fitzler
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